WORKSTATION FOR INTEGRATING AUTOMATED CHEMICAL ANALYZERS

Background of the Invention

Area of the Art

The invention relates generally to automated chemical analyzers, and specifically to workstations for integrating automated chemical analyzers.

Description of the Prior Art

Automated chemical analyzers are commonly used in clinical chemistry sampling and analyzing applications. Automated analytical equipment, such as automated analytical chemistry workstations, can efficiently perform clinical analysis on a large number of samples, with tests being run concurrently or within short time intervals. Efficiencies result in part because of the use of automated sample identification and tracking. This equipment can automatically prepare appropriate volume samples and can automatically set the test conditions needed to perform the scheduled tests. Test conditions can be independently established and tracked for different testing protocols simultaneously in progress within a single test station, facilitating the simultaneous execution of a number of different tests based on different chemistries and requiring different reaction conditions. Automated analytical equipment is particularly well-suited for high volume testing environments, such as those existing in many hospitals and in centralized testing laboratories, because the automatic sample handling allows for more precise sample identification and sample tracking. Automatic handling and tracking of samples significantly reduces the opportunity for human error or accidents that can lead to either erroneous test results or undesirable contamination.

An example of such an automated clinical chemistry system is provided by U.S. Patent No. 5,575,976 to Choperena, *et al.*, which describes embodiments of the Access® Special Chemistry Analyzer presently available through the Clinical Chemistry Division of Beckman Coulter, Inc., located in Brea, California. Another automated chemistry analyzer is the SYNCHRON LX®20 General Chemistry Analyzer, as described in U.S. Patent No. 5,863,506 to Farren, U.S. Patent No.

5,833,925 to Hsu, *et al.*, and in U.S. Patent Application Serial No. 08/748,135 to Robins, *et al.*, entitled "Pressure Detector for Chemical Analyzers," and in U.S. Patent Application No. 08/746,649 to Fechtner, *et al.*, "Automatic Chemistry Analyzer with Sample Cup Piercing Assembly," which is also presently available through the Clinical Chemistry Division of Beckman Coulter, Inc., located in Brea, California. These chemistry systems can provide automated analysis of a number of samples.

In many situations, there is a need to perform a series of analysis by various different analyzers. For example, it is often required that a general chemical analysis be performed and then followed by a more specific immunodiagnostic analysis. In addition, reflex testing of a sample is often needed for a particular analysis.

Therefore, it is desirable to provide a workstation for integrating two or more automated chemical analyzers for performing a series of chemical analysis and having the capacity of facilitating reflex testing.

Summary of the Invention

It is an object of the present invention to provide a workstation for integrating two or more automated chemical analyzers.

It is also an object of the present invention to provide a workstation for integrating two or more automated chemical analyzers where the automated chemical analyzers will have a single common sample input area.

It is another object of the present invention to provide a workstation for integrating two or more automated chemical analyzers where the automated chemical analyzers will have a single common control console.

It is an additional object of the present invention to provide a workstation for integrating two or more automated chemical analyzers that can facilitate automated reflex testing from one automated chemical analyzer to another.

It is still an object of the present invention to provide a workstation for integrating two or more automated chemical analyzers with the function of sampling from closed sample tubes.

It is a further object of the present invention to provide a workstation for integrating two or more automated chemical analyzers with the capacity of rapid loading of STAT samples.

The objects and advantages of the present invention are achieved in a workstation for two or more automated analyzers of the present invention. The workstation of the present invention includes a sample rack handler assembly having a single common sample rack input area for loading sample racks for one of the two or more automated analyzers, a sample rack bypass area for passing sample racks to be processed by the one of the two or more automated analyzers, and a sample rack output area for off-loading sample racks after being processed by the one of the two or more automated analyzers.

The workstation of the present invention also includes a sample aliquoting assembly having a cap-piercing station for piercing caps of closed sample tubes contained in the sample racks, and a sample pipetter station for pipetting sample aliquot and dispensing the sample aliquot to aliquot vessels for processing by another one of the two or more automated analyzers.

The workstation of the present invention further includes an internal shuttle for shuttling the sample racks between the sample rack input area, the sample rack bypass area, the cap-piercing station and the sample pipetter station, and an external shuttle for shuttling the sample racks between the sample rack input area, the sample rack bypass area, and the one of the two or more automated analyzers.

The workstation of the present invention additionally includes a pick-and-place mechanism for transporting the aliquot vessels between the sample pipetter station and the other one of the two or more automated analyzers.

Such an arrangement has been found to provide a number of advantages. As explained in greater detail below, the workstation of the present invention integrates two or more automated chemical analyzers for performing a series of chemical analysis. The workstation of the present invention also provides a single common sample input area and a single control console for the integrated automated chemical analyzers. In addition, the workstation of the present invention can facilitate automated reflex testing from one automated chemical analyzer to another. Furthermore, the workstation of the present invention has the function of sampling from closed sample tubes and the capacity for rapid loading of STAT samples.

The invention is defined in its fullest scope in the appended claims and is described below in its preferred embodiments.

Description of the Figures

The above-mentioned and other features of this invention and the manner of obtaining them will become more apparent, and will be best understood by reference to the following description, taken in conjunction with the accompanying drawing(s). The(se) drawing(s) depict(s) only a typical embodiment of the invention and do not therefore limit its scope. The drawing(s) serve(s) to add specificity and detail, in which:

FIGURE 1 is an illustrative block diagram showing two automated analyzers integrated by a preferred embodiment of the workstation of the present invention;

FIGURE 2 is an illustrative top view showing the layout of the preferred embodiment of the workstation present invention;

FIGURE 3 is an illustrative perspective view of a sample rack handler assembly of the workstation of the present invention;

FIGURE 4 is an illustrative perspective view of a sample aliquot assembly of the connector unit of the workstation of the present invention; and

FIGURE 5 is an illustrative block diagram showing the common control system of the workstation of the present invention and the integrated automated analyzers.

Detailed Description of the Invention

The present invention is directed to a new and unique workstation for integrating two or more automated chemical analyzers. In accordance with embodiments of the present invention, the workstation of the present invention includes a sample rack handler assembly and a sample aliquoting assembly.

The sample rack handler assembly has a single common sample rack input area for loading sample racks for the two or more automated analyzers, a sample rack bypass area for passing sample racks to be processed by one of the two or more automated analyzers, and a sample rack output area for off-loading sample racks after being processed by the one of the two or more automated analyzers. This sample rack handler assembly provides the workstation of the present invention a single common sample input area for the integrated automated chemical analyzers.

The sample aliquoting assembly has a cap-piercing station for piercing caps of closed sample tubes contained in the sample racks, and a sample pipetter station for

pipetting sample aliquot and dispensing the sample aliquot to aliquot vessels for processing by one of the two automated analyzers. This sample aliquoting assembly of the workstation allows closed tube sampling on the combined automated analyzers.

The workstation also includes an internal shuttle for shuttling the sample racks to be processed by the one of the two automated analyzers from the sample rack input area to the sample rack bypass area, and also for shuttling the sample racks to be aliquoted from the sample rack input area to the sample pipetter station, and, further, for shuttling sample racks to and from the cap piercing station.

The workstation further includes an external shuttle for shuttling the sample racks to be processed by the one of the two automated analyzers from the sample rack bypass area to the one of the two automated analyzers, and also for shuttling the sample racks from the one of the two automated analyzers back to the sample rack output area after being processed by the one of the two automated analyzers.

The workstation additionally includes a pick-and-place mechanism for transporting the aliquot vessels between the sample pipetter station and the other one of the two automated analyzers.

The workstation further includes a common computerized control system for controlling the workstation and the two or more analyzers integrated by the workstation. The control system is electrically and electronically coupled to the control electronics of the workstation and the analyzers, so that various tasks can be performed, including but not limited to, sample programming, reagent load control, system setup and status, maintenance and diagnostics. The workstation of the present invention allows automatic reflex testing from one analyzer to the other.

Having thus provided an overview of certain embodiments of the present invention, this specification now provides a more detailed discussion of preferred embodiments of the present invention with particular reference to the drawings. Referring to Figures 1 and 2, there is shown at workstation **2** a workstation of the present invention for integrating, for example, an automated general chemical analyzer **10**, such as a Synchron LX 20 General Chemistry System, and an automated immunodiagnostic analyzer **20**, such as an Access 2 Heterogeneous Immunochemistry System, both manufactured by and available from Beckman Coulter, Inc., the Assignee of this patent application. It should be understood that the workstation of the present

invention may also be used for integrating other types of automated chemical or immunochemistry analyzers, and the integration of the analyzers is within the skill of the art in view of the present disclosure.

Typically, the automated general chemical analyzer **10** has, among other components, a sample wheel **12** for receiving input sample racks for general chemical analysis. Similarly, the automated immunodiagnostic analyzer **20** also has, among other components, a sample wheel **22** for receiving input sample containers for immunodiagnostic analysis.

The workstation **2** of the present invention has the following main components: a computer console, a sample rack handler assembly **30**, and a sample aliquot assembly **50**.

Referring to Figures 1, 2 and 3, there is shown the sample rack handler assembly **30** of the workstation **2** of the present invention. The sample rack handler assembly **30** provides a single point of sample entry for the entire integrated system. It has the following main component parts: an input area **32**, a bypass area **34**, an output area **36**, an external shuttle **38**, an internal shuttle **40**, and a bar code reader (BCR) **42**.

The input area **32** provides a sample rack input path for the workstation **2**. The bypass area **34** provides a sample rack path from the workstation **2** to the general chemical analyzer **10**. The output area **36** provides a sample rack output path.

The external shuttle **38** shuttles the sample racks from the bypass area **34** to the sample wheel **12** of the general chemical analyzer **10**, and also shuttles the sample racks back from the sample wheel **12** of the general chemical analyzer **10** to the output area **36**, or to the input area **32**, if reflex testing is required. The internal shuttle **40** shuttles sample racks from the input area **32** to the bypass area **34**, and also shuttles sample racks further to the sample aliquot assembly **50** of the workstation **2**. The structural and functional arrangements of the shuttles **38** and **40** conform to existing arrangements known to those of ordinary skill in the art, and therefore will not be described in detail here.

The bar code reader (BCR) **42** is used to obtain identification of the sample racks. It is electronically coupled to the computer console to provide the sample rack identification and test information to the computer console for sample programming. The structural and functional arrangements of the BCR **42** conform to existing

arrangements known to those of ordinary skill in the art, and therefore will not be described in detail here.

Referring to Figures 1, 2, and 4, there is shown the sample aliquot assembly **50** of the workstation **2** of the present invention. It has the following main component parts: a closed cap-piercing station **52**, a sample pipette station **54**, a pick-and-place mechanism **56**, and an aliquot sample wheel **58**.

Sample racks from the sample rack handler assembly **30** are shuttled to the closed cap-piercing station **52** of the sample aliquot assembly **50** by the internal shuttle **40**. The closed cap-piercing station **52** is used for piercing the closed caps of sample tubes. A detailed description of the structural and functional arrangements of the closed cap-piercing station is provided in the assignee's co-pending patent application for "Sample Loading and Handling Interface to Multiple Chemistry Analyzers," with serial number 09/335,363. Alternatively, another embodiment of a closed cap-piercing station, described in the assignee's co-pending patent application for "Cap Piercing Station for Closed Container Sampling System," with serial number 09/599,305 may also be used. The contents of the two patent applications are incorporated herein in their entirety by reference.

The sample pipette station **54** is used to aliquot a required amount of sample from a pierced sample tube and then dispense the aliquoted sample into a aliquot vessel positioned on the aliquot vessel storage tray **64**. The sample probe carriage is driven by aliquot probe carriage drive motors **60**. An aliquot probe wash station **62** is provided for washing the aliquot probe. The structural and functional arrangements of the sample pipette station **54** conform to existing arrangements known to those of ordinary skill in the art, and therefore will not be described in detail here.

The pick-and-place mechanism **56** is used to: (a) transfer aliquot vessels containing aliquoted samples to the sample wheel **22** of the immunodiagnostic analyzer **20**; and (b) off-load aliquot vessels from the sample wheel **22** of the immunodiagnostic analyzer **20** to a solid waste container. The pick-and-place mechanism **56** is carried on an assembly gantry **66** and driven by pick-and-place carriage motors **68**. A detailed description of the structural and functional arrangements of the pick-and-place mechanism **56** is provided in the assignee's co-pending patent application for "Sample Loading and Handling Interface to Multiple

Chemistry Analyzers," with serial number 09/335,363, the contents of which are incorporated herein by reference. Alternative embodiments are also described in the assignee's co-pending patent application for "Method and System for Picking and Placing Reaction Vessels" and are incorporated herein by reference.

Referring to Figure 5, there is shown a common computerized system **70** for controlling the workstation **2** of the present invention, the automated general chemical analyzer **10**, and the automated immunodiagnostic analyzer **20**, which are integrated by the workstation **2** of the present invention.

The control system **70** utilizes a single common computerized center control console **72** for both the automated general chemical analyzer **10** and the automated immunodiagnostic analyzer **20**, as well as for the workstation **2**. The computerized center control console **72** is electrically and electronically coupled to the control electronics of the workstation **2** and the two integrated automated analyzers **10** and **20**, so that various tasks can be performed, including sample programming, reagent load control, system setup and status, maintenance, and diagnostics.

Optionally, the computerized center control console **72** may be connected to a laboratory information system **74**. In addition, a maintenance sub-console **76** may be used for each automated analyzer.

As an example, the control system **70**, shown in Figure 5, includes a sub-console **76** for maintenance of the automated general chemical analyzer **10**, in which case the main console **72** and the sub-console **76** are all electrically and electronically coupled to the control electronics of the automated general chemical analyzer **10**.

The workstation **2** of the present invention is also constructed for housing facilities for wash solution, air pressure, vacuum for waste handling, power supplies, electronics for monitoring and control of the various modules, and environmental control, as required. The structural and functional arrangements for housing these facilities and of facilities themselves conform to existing arrangements and details known to those of ordinary skill in the art, and therefore will not be described in detail here.

The functions and operations of workstation **2** will be described as follows:

1. Loading Samples to Workstation **2**

An operator loads sample racks onto the sample rack input area **32** of the sample rack handler assembly **30**. The first sample rack is shuttled from the input area **32** by the internal shuttle **40**, passing the bypass area **34**, to the BCR **42**, where the sample identification, sector number, and tube presence are determined.

Based on this identification information from BCR **42**, and data retrieved from the general chemical analyzer **10** and the immunodiagnostic analyzer **20**, the computerized control system of the workstation **2** will determine: (a) whether there is a pending analysis to be performed by the immunodiagnostic analyzer **20**; and (b) whether the caps or stoppers of the sample tubes in the sample rack have previously been pierced.

If the caps or stoppers of the sample tubes have not been previously pierced, then the sample rack is shuttled to the closed cap-piercing station **52** of the sample aliquot assembly of the workstation **2**, where the caps or stoppers of the sample tubes are pierced.

If no analysis is pending at the immunodiagnostic analyzer **20**, then the computerized control system of the workstation **2** will ascertain whether the bypass area **34** is full.

If the bypass area **34** is full, then the sample rack will wait until the sample racks already in the bypass area **34** are processed.

If the bypass area **34** is not full, then the sample rack is placed onto the bypass area **34** for processing by the general chemical analyzer **10**.

If there is an analysis pending at the immunodiagnostic analyzer **20**, then the sample rack is further shuttled to the sample pipette station **54** for sample aliquoting, where a sample aliquot is made. The computerized control system of the workstation **2** will then ascertain whether the bypass area **34** is full.

If the bypass area **34** is full, then the sample rack will wait until the sample racks already in the bypass area **34** are processed.

If the bypass area **34** is not full, then the sample rack is placed onto the bypass area **34** for processing by the general chemical analyzer **10**.

This process is repeated until all sample racks have been processed.

2. Sample Aliquoting for Immunodiagnostic Analyzer **20**

The sample pipette station **54** of the sample aliquoting assembly **50** of the workstation **2** withdraws a predetermined volume of sample from the sample tube, depending upon the requirements of the immunodiagnostic analyzer **20**. The sample pipette station **54** then dispenses the withdrawn sample into an available aliquot vessel.

The aliquoted sample in the aliquot vessel is stored for a predetermined period of time or until there are a predetermined number of aliquot vessels containing aliquoted samples to be analyzed by the immunodiagnostic analyzer **20**.

3. Loading Samples to the Immunodiagnostic Analyzer **20**

The workstation **2** of the present invention will coordinate the queuing of the samples to be run on the immunodiagnostic analyzer **20**. It communicates with the immunodiagnostic analyzer **20** to control the indexing of the sample wheel **22**, and transfers sample identification and test information to the immunodiagnostic analyzer **20**.

The pick-and-place mechanism **56** of the workstation **2** will load the aliquot vessels containing aliquot from the sample pipette station **54** to the sample wheel **22** of the immunodiagnostic analyzer **20**. When all aliquot vessels containing aliquot have been loaded onto the sample wheel **22** of the immunodiagnostic analyzer **20**, the test will be initiated.

4. Off-Loading Samples from the Immunodiagnostic Analyzer **20**

When all sampling requirements of the aliquoted sample have been completed by the immunodiagnostic analyzer **20**, the aliquot vessels containing the completed aliquot sample will be moved from the sample wheel **22** of the immunodiagnostic analyzer **20** to the waste container of the workstation **2** by the pick-and-place mechanism **56**.

5. Loading of STAT Samples

Sample racks containing STAT samples for both the general chemical analyzer **10** and the immunodiagnostic analyzer **20** are treated in the same manner.

When there is no routine rack in the bypass area **34** of the workstation **20**, the STAT rack will be placed onto the rack input area **32**. The internal shuttle **40** will shuttle the STAT rack through the BCR **42** and to the cap-piercing station **52** and then to the sample pipette station **54**. The control system will immediately interrupt the immunodiagnostic analyzer **20** to load the STAT aliquot, if any are available.

The STAT rack is then shuttled to the rack bypass area **34** of the workstation **2**, from there it is shuttled by external shuttle **38** to the sample wheel **12** of the general chemical analyzer **10**.

When there are routine racks in the bypass area **34** of the workstation **20**, the STAT rack will also be placed onto the rack input area **32**. The internal shuttle **40** will shuttle these routine racks back to the rack input area **32** to clear out the bypass area **34**. The internal shuttle will then shuttle the STAT rack through the BCR **42**, to the cap-piercing station **52**, and then to the sample pipette station **54**. The control system will immediately interrupt the immunodiagnostic analyzer **20** to load the STAT aliquot, if any are available.

The STAT rack is then shuttled to the rack bypass area **34** of the workstation **2**, and from there it is shuttled by the external shuttle **38** to the sample wheel **12** of the general chemical analyzer **10**.

6. Reflex Testing from the General Chemical Analyzer **10** to the Immunodiagnostic Analyzer **20**

When a test performed by the general chemical analyzer **10** triggers or requires a reflex test by the immunodiagnostic analyzer **20**, the rack containing the sample for which the reflex test is to be performed is shuttled back from the sample wheel **12** of the general chemical analyzer **10** to the rack input area **32** of the workstation **2** by the external shuttle **38** of the workstation **2**.

The workstation **2** then routes the reflexed sample rack to the immunodiagnostic analyzer **20**, utilizing the normal sample aliquoting and loading sequences, as described in Paragraphs 3 and 4 above. The control system of the workstation **2** will also communicate the reflex test information to the immunodiagnostic analyzer **20**.

The above description of the functions and operations of workstation **2** of the present invention is provided for illustration purposes. With proper programming, these basic functions and operations may be combined, modified, and supplemented to perform various tasks required by the general chemical analyzer **10** and/or the immunodiagnostic analyzer **20**.

The workstation of the present invention has many unique and advantageous features, including the integration of two or more automated chemical analyzers for

performing a series of chemical analysis, the provision of a single common sample input area, and a single control console for the integrated automated chemical analyzers.

Additionally, the workstation of the present invention is capable of sampling from closed sample tubes and also capable of the rapid loading of STAT samples. Moreover, the workstation of the present invention is capable of facilitating automated reflex testing from one automated chemical analyzer to another.

The present invention may be embodied in other specific forms without departing from its essential characteristics. The described embodiment is to be considered in all respects only as illustrative and not as restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of the equivalence of the claims are to be embraced within their scope.